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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,360	LI ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8-16,20-42,51-57 and 59-80* is/are pending in the application.

4a) Of the above claim(s) *4,14,16,39,41,51-57,67,68,70,71,75,77 and 80* is/are withdrawn from consideration.

5)☒ Claim(s) *15* is/are allowed.

6)☒ Claim(s) *1-3,8-13,20-38,40,42,59-66,69,72-74,76,78 and 79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1) Claims 1 to 4, 8 to 16, 20 to 42, 51 to 57 and 59 to 80 are pending in the instant application. Claims 1, 4, 13, 20, 39 to 41, 51, 57 and 59 have been amended, claims 5 to 7, 17 to 19, 43 to 50 and 58 have been canceled and claim 80 has been added as requested by Applicant in the correspondence filed 30 May of 2008.

Election/Restrictions

2) Claims 4, 14, 16, 39, 41, 51 to 57, 67, 68, 70, 71, 75, 77 and 80, and claims 1 to 3, 8 to 13, 20 to 38, 40, 42, 59 to 66, 72 to 74, 76, 78 and 79 in so far as they relate to a recited amino acid sequence other than SEQ ID NO:64, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 30 May of 2008. .

The traversal is on the ground(s) that the various amino acid sequences recited in the instant claims reflect a unifying inventive concept because they relate to T1R proteins of feline origin. This is not found persuasive because isolated nucleic acids encoding mammalian T1R proteins, and the proteins encoded thereby, were known in the art prior to the instant invention. Further, species of origin is not an art-recognized distinguishing special technical feature. Because most, if not all, of the individual amino acid sequences recited in the claims are each more closely related to one or more known T1R sequences from other mammals, than to the other recited sequences, as clearly demonstrated by Figures 2A to 2D and the phylogenetic tree presented in Figure 3 of the instant application, they do not share a common structural feature of

combination of features that distinguishes them as a group from T1R proteins of the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Specification

3) The disclosure is objected to because there is text missing from the right column of Table 4 on page 68. Appropriate correction is required.

4) The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable code in paragraphs 0026, 0058, 0195 and 0206. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01(p), which states that:

> "When a patent application with embedded hyperlinks and/or other forms of browser-executable code issues as a patent (or is published as a patent application publication) and the patent document is placed on the USPTO web page, when the patent document is retrieved and viewed via a web browser, the URL is interpreted as a valid HTML code and it becomes a live web link. When a user clicks on the link with a mouse, the user will be transferred to another web page identified by the URL, if it exists, which could be a commercial web site. USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. If hyperlinks and/or other forms of browser-executable code are embedded in the text of the patent application, examiners should object to the specification and indicate to applicants that the embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion."

Correction is required.

Claim Objections

5) Claims 1, 13, 62, 73 and 74 are objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

> "Since the decisions in In re Weber **,198 USPQ 328 (CCPA 1978); and In re Haas, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, In re Harnish , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); Ex Parte Hozumi , 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

The various alternate embodiments recited in these claims do not reflect a common inventive concept because the different sequences or combination of proteins recited therein do not share a common utility that is based upon a common substantial structural feature or combination of features that distinguishes all of the recited embodiments, as a group, from related sequences or protein complexes of the prior art.

6) Claims 13, 20 and 22 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependent claim can not conceivably be infringed without infringing any of the claims from which it depends. Claim 13, for example, can not properly depemnd from claim 1 because claim 13 can be infringed by an isolated polypeptide that clearly fails to infringe claim 1, which is drawn to an isolated and purified polynucleotide. See M.P.E.P. 608.01(n)III.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7) Claims 1 to 3, 8 to 13, 21 to 38, 40, 42, 59 to 66, 69, 72 to 74, 76, 78 and 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In so far as these claims require "a variant of the polynucleotide of SEQ ID NO:62 or SEQ ID NO :63 having at least 95% homology to the polynucleotide of SEQ ID NO:62 or SEQ ID NO:63 and encoding a polypeptide having substantially the same biological activity as a polypeptide encoded by the nucleotide sequence of SEQ ID NO:62 or SEQ ID NO:63, respectively", the only biologically active protein that is described in the instant specification as being encoded by SEQ ID NO:62 or SEQ ID NO:63 of the instant application comprises the amino acid sequence presented therein as SEQ ID NO:64. Whereas the nucleotide sequence presented in SEQ ID NO:62 or 63 can be translated in any one of three different reading frames from any one of a plurality of start codons, yielding amino acid sequences having absolutely no structural relationship to SEQ ID NO:64, the only functional protein described in the specification as being encoded by the referenced sequence comprises the amino acid sequence of SEQ ID NO:64.

In the decision of *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Whereas the instant specification provides a detailed description of an isolated DNA encoding a particular feline taste receptor comprising SEQ ID NO:64 and having very specific physical and structural properties, the instant specification does not describe even a single functional feline T1R2 receptor protein lacking all or a significant portion of the amino acid sequence presented in SEQ ID NO:64.

8) Claims 1 to 3, 8 to 13, 21 to 38, 40, 42, 59 to 66, 69, 72 to 74, 76, 78 and 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. These claims encompass subject matter that was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims encompass a binding assay that can employ a nucleic acid encoding a feline "T1R2" protein having other than the entire amino acid sequence presented in SEQ ID NO:64 of the instant application, an isolated nucleic acid encoding that protein and the protein encoded thereby. As indicated in the preceding rejection, claim 1 encompasses a polypeptide having no sequence identity to SEQ ID NO:64. The only manner described in the instant specification of using the claimed products is in the identification of compounds that have potential utility because of their ability to agonize or antagonize the feline T1R2 protein described therein. The claimed invention is only useful in so far as the T1R2 protein employed in such an assay responds in a manner that is predictive of an authentic physiological response. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and

physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

One of ordinary skill in the art of receptor biology would not reasonably believe that the majority of physical peptide embodiments having no sequence identity to SEQ ID NO:64 are going to be functional, much less be capable of producing an authentic response. Because the instant specification does not identify those amino acid residues in SEQ ID NO:64 which are critical to the structural and functional integrity of a feline T1R2 receptor protein comprising that sequence, identify a structurally analogous protein for which this information is known and could be applied to the instant protein by extrapolation, or even provide a single working example of an intentionally modified feline T1R2 protein of the instant invention, an artisan can not change even a single residue within the amino acid sequence of SEQ ID NO:64 and predict the effects of that change on the performance of that protein “by resort to known scientific law”. Therefore, an artisan would have to engage in a substantial amount of experimentation in order to ascertain the structural and functional information from SEQ ID NO:64 that would be needed to produce “a polypeptide having at least 95% identity to the amino acid sequence of SEQ ID NO:64 an having at least one sequence variation of SEQ ID NO:64 wherein said variation confers modified taste perception to one or more taste stimuli relative to a polypeptide of SEQ ID NO:64”. Unless one can predict, with reasonable confidence, that an intentionally modified feline T1R2 protein is going to produce a response that is predictive of a native feline T1R2 protein, the information obtained from a process that uses that modified protein is of no practical value.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9) Claims 1 to 3, 8 to 13, 20 to 38, 42, 59 to 66, 69, 72 to 74, 76, 78 and 79 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9.1) Claim 1 is vague and indefinite because the metes and bounds of the limitation "substantially complementary" are undeterminable. Claims 2, 3, 8 to 13, 21 to 38, 42, 59 to 66, 69, 72 to 74, 76, 78 and 79 are vague and indefinite in so far as they depend from claim 1 for this element.

9.2) Claim 20 is vague and indefinite because the metes and bounds of the limitation "specifically hybridizes to" are undeterminable.

9.3) Claims 69 and 72 are vague and indefinite because the recitation "comprising at least one polypeptide of SEQ ID NO:64" implies that there is more than one amino acid sequence in SEQ ID NO:64 or that the polypeptide requires less than the entire amino acid sequence presented in SEQ ID NO:64. Further, there is no antecedent basis for a "polypeptide of SEQ ID NO:64" because SEQ ID NO:64 is an amino acid sequence, which is nothing more than a property of a compound, whereas a polypeptide is a material compound.

Allowable Subject Matter

10) Claim 15 is allowable as written.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John D. Ulm/
Primary Examiner, Art Unit 1649